



Atty. Dkt. No. 041673-0206

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Knowlton et al.

Title:

Method and Materials for Use in

Diagnosing Viral Myocarditis

Appl. No.:

10/591,092

Filed:

August 29, 2006

Examiner:

Art Unit:

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.

(Printed Name)

(Signature)

(Signature)

(Date of Deposit)

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

## RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-0872.

Respectfully submitted,

Date 1-26-9001

**FOLEY & LARDNER LLP** 

Customer Number: 30542

Telephone:

(858) 847-6720

Facsimile:

(858) 792-6773

Stacy L. Taylor

Attorney for Applicant

Registration No. 34,842

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Substitu	ite for form 1449/P	то	Complete if Known		
,,,,, INFORM	ATION DISCLOS	SURE	Application Number	10/591,092	
FEB U 2 2007 STATEMENT BY APPLICANT			Filing Date	08-29-2006	
			First Named Inventor	Kirk Knowlton	
<b>1</b> 0/			Art Unit	Unknown	
TRADPANTSe as mai	ny sheets as nec	essary)	Examiner Name	Unknown	
Sheet 1	of	3	Attorney Docket Number	041673-0206	

U.S. PATENT DOCUMENTS						
Examiner Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant		
Initials*		Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear	
	A1	5,571,698	November 5, 1996	Ladner et al.		
	A2	6,057,098	May 2, 2000	Buechler et al.		

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Application Document Serial Number-Kind Code <sup>2</sup> (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials* No.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
. , .	A3	Cabily, et al. "Generation of Antibody Activity from Immunoglobulin Polypeptide Chains Produced in Escherichia Coli", <i>Proc. Natl. Acad. Sci. USA</i> , <u>81</u> :3273, 1984	
	A4	Cwirla et al., "Peptides on Phage: A vast library of peptides for identifying ligands", Proc. Natl. Acad. Sci. USA 87, 6378-82, 1990	
	A5	Devlin et al., "Random Peptide Libraries: A Source of Specific Protein Binding Molecules", Science 249, 404-6, 1990	
	A6	Feldman and McNamara, "Myocarditis", New Engl. J. Med., 343:1388-1398, at 1393 (2000)	

	·	 	
Examiner Signature		Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant: 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

	Substitute f	or form 1449/	PTO		Complete if Known		
	INFORMATI	ON DISCLO	SURE	Application Number	10/591,092		
	STATEMENT BY APPLICANT			Filing Date	08-29-2006		
				First Named Inventor	Kirk Knowlton		
				Art Unit	Unknown		
(use as many sheets as necessary)			cessary)	Examiner Name	Unknown		
Sheet	2	of	3	Attorney Docket Number	041673-0206		

NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	No.1 ltem (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number publisher, city and/or country where published.						
	A7	Fujiwara et al., "Synthesis of Human C-Type Natriuretic Peptide 22 Using Chlorotrityl Resin and Tetrafluoroboric Acid Deprotection", Chem. Pharm. Bull. (Tokyo) 44: 1326-31, 1996					
_	A8	Huse, <i>et al.,</i> "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda", <i>Science</i> , <u>246</u> :1275-1281, 1989	<del> </del>				
	A9	Huse et al., "Application of a Filamentous Phage pVIII Fusion Protein system Suitable for Efficient Production, Screening, and Mutagenesis of F(ab) Antibody Fragments", J. Immunol. 149, 3914-3920 (1992)					
	A10	Ishiwata, et al., "Studies of 18F-labeled pyrimidines", Eur.J. Nucl. Med., 9:185-189, 1984					
	A11	Keough, et al, "An Improved Method For Synthesis and Purification of 125I or 131I labeled Carrier-Free 5-IODO-1'-Deoxyuridine", J.Labeled Compound Radiopharm., 14:83-90, 1978					
	A12	Kiso et al., "Solution-Phase Synthesis of Porcine Brain Natriuretic Peptide (pBNP) Using S- Trimethylacetamido-methylcystein", Chem. Pharm. Bull. (Tokyo) 38: 1192-99, 1990					
	A13	Kubota, et al., "Differential Diagnosis of AH109A Tumor and Inflammation by Radioscintigraphy with L-[Methyl-11C] methionine", Jpn.J.Cancer Res., 80:778-782, 1989					
	A14	Makrigiorgos, et al., "Inhomogeneous Deposition of Radiopharmaceuticals at the Cellular Level: Experimental Evidence and Dosimetric Implications", <i>J.Nucl.Med.</i> , 31:1358-1363, 1990					
	A15	Mostafavi et al, "Synthesis, Purification and Biological Activity of (SER10-Phosphatidyl)-Urodilatin (Phosphourodilatin), Biomed. Pept. Proteins Nucleic Acids 1: 255-60, 1995					
	A16	Mullinax, et al., "Identification of human antibody fragment clones specific for tetanus toxoid in a bacteriophage λ immunoexpression library", <i>Proc. Natl. Acad. Sci.</i> , <u>87</u> :8095-8099, 1990					
	A17	Riechmann, et al., "Reshaping Human Antibodies for Therapy", Nature 332:323, 1988					
	A18	Scott and Smith, "Searching for Peptide Ligands with an Epitope Library", Science 249, 386-88, 1990					
	A19	Shaw, et al., "Characterization of a Mouse/Human Chimeric Monoclonal Antibody (17-1A) to a Colon Cancer Tumor-Associated Antigen", J. Immun., 138:4534 (1987)					
	A20	Sheng, et al.,"Cardiotrophin 1 (CT-1) Inhibition of Cardiac Myocyte Apoptosis Via A Mitogen=activated Protein Kinase-dependent Pathway", J.Biol.Chem., 272:5783-5791 (1997					

Examiner Signature	Date Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08 (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

7	Substitute fo	or form 1449/	PTO	Complete if Known		
	INFORMATIO	ON DISCLO	SURE	Application Number	10/591,092	
STATEMENT BY APPLICANT			CANT	Filing Date	08-29-2006	
				First Named Inventor	Kirk Knowlton	
				Art Unit	Unknown	
(use as many sheets as necessary)			cessary)	Examiner Name	Unknown	
Sheet	3	of	3	Attorney Docket Number	041673-0206	

		NON PATENT LITERATURE DOCUMENTS	·
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A21	Spira, et al., "The Identification of Monoclonal Class Switch Variants by Sib Selection and an ELISA Assay", J. Immunol. Methods, 74:307, 1984	
	A22	Sun, L.K., et al., "Chimeric Antibody With Human Constant Regions and Mouse Variable Regions Directed Against Carcinoma-Associated Antigen 17-1A", Proc. Natl. Acad. Sci. USA, 84:214-218 (1987)	
	A23	Steplewski, et al.,"Isolation and Characterization of Anti-monosialoganglioside Monoclonal Antibody 19-9 Class-Switch Variants", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , <u>82</u> :8653, 1985	
	A24	Ward et al., "Binding Activities of a Repertoire of Single Immunoglobulin Variable Domains Secreted from Escherichia Coli", (1989) <i>Nature</i> 341:544-546)	
	A25	Wilson et al., "Simplified Conjugation Chemistry for Coupling Peptides to F(ab') Fragments: Autologous Red Cell Agglutination Assay for HIV-1 Antibodies", (1994) J. Immunol. Methods 175:267-273	
	A26	Yarmush M.L, et al., "Coupling of Antibody-Binding Fragments to Solid-Phase Supports: Site-Directed Binding of F(ab')2 Fragments", (1992) J. Biochem. Biophys. Methods 25:85-97	

Examiner Signature	Date Considered	
	)	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.